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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,726	12/21/2001	Wen-Hwa Lee	17726A-000420US	4418
20350	7590	05/06/2005	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			WILSON, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/028,726

Applicant(s)

LEE ET AL.

Examiner

Michael C. Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 49-56 is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input checked="" type="checkbox"/> Other: <u>Reasons for allowance.</u> |

Quayle Action

This application is in condition for allowance except for the following formal matters:

The amendment filed 3-3-05 is not in the proper format. Claims 1-48 are not listed as being cancelled.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

REASONS FOR ALLOWANCE

The allowed claims have support in claims 41-47 as originally filed, and pg 43, 1st ¶. Claims 41-47 as originally filed can also be found in 07/265,829 and suppression of the neoplastic phenotype is found on pg 53, line 1, of '829. Thus, the allowed claims have priority to 10-31-88.

The following is an examiner's statement of reasons for allowance:

Claim Rejections - 35 USC § 102

The rejection of claims 49-56 under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter based on Lee and Chen (US patent 5,532,220) has been withdrawn.

Applicants (Wen-Hwa Lee, Huie-Jen Su Huang, and Eva Y.H.P. Lee) claim a method of treating mammalian cancer cells lacking endogenous wild-type RB protein by introducing a wild-type RB gene into the cells, thereby suppressing the cells' neoplastic phenotype.

Wen-Hwa Lee and Phang-Lang Chen (US Patent 5,532,220) invented a method of treating mammalian cancer cells lacking endogenous wild-type p53 protein by introducing a wild-type p53 gene into the cells, thereby suppressing the cells' neoplastic phenotype. Wen-Hwa Lee and Phang-Lang Chen described the function of the RB protein and introducing a wild-type copy of RB into retinoblastoma cells, which suppressed their tumorigenic properties (col. 5, lines 7-10). Wen-Hwa Lee and Phang-Lang Chen state RB and p53 had equivalent functions (col. 5, line 26-28). Wen-Hwa Lee and Phang-Lang Chen did not teach the p53 gene was derived from the RB gene.

Applicants argue: "As noted previously, the claims of the '220 patent are directed to treatment of cancer cells lacking wild-type p53 by introducing a wild-type p53 gene into the cells. In the Office Action the Examiner asserts that 'p53 is a portion of the RB gene.' The Examiner provides no evidence to support this statement. Applicants are not aware of any publication that makes such a claim. The absence of evidence that p53 is indeed a portion of RB, the rejection cannot be maintained."

While p56 is a portion of the RB gene, p53 as claimed in the instant invention is not a portion of the RB gene as previously asserted by the examiner. Evidence is provided by Xu (US Patent 5,912,236), who describes the p110 full length RB gene (col. 3, line 10) and the p56 fragment of the RB gene (col. 3, lines 18-21)(see col. 2, line 55,

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through col. 3, line 21) and separately describes the p53 gene (col. 5, line 6-34). No evidence can be found stating the p53 gene as claimed by Lee and Chen in '220 is a wild-type RB gene as claimed in the instant invention.

Thus, the wild-type RB tumor suppressing gene required in the claims encompasses the p56 RB gene fragments but does not encompass the p53 gene described by Lee and Chen in US Patent 5,532,220.

The second rejection of claims 49-56 under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter has been withdrawn because the petition to change inventorship under 37 CFR 1.48 has been entered. A letter from petitions branch was sent 4-25-05 regarding the decision.

Double Patenting

The rejection of claims 49-56 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,532,220 has been withdrawn for reasons above under 102(f) regarding '220.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

A handwritten signature in black ink, consisting of a series of vertical, wavy lines followed by a horizontal flourish.

MICHAEL WILSON
PRIMARY EXAMINER